

Adverse reactions identification and documentation

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Policy

All adverse reactions to medicines (including contrast media), vaccines, therapeutic devices (including latex and wound dressings), complementary therapies and foods will be identified and documented.

Please note:

- Refer to the CDHB Food Allergies Policy regarding policy requirements for food related reactions (currently in development)
- All reactions to therapeutic devices i.e. latex, dressings, solutions need to be documented within the patients' current clinical notes and care plan.

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Purpose

- To minimise harm by preventing exposure to, or the
- Re-administration of, a harmful substance.
- To minimise situations where therapy is withheld unnecessarily.
- To contribute to post-marketing surveillance and drug safety.

Scope

- All relevant administration staff (including ward clerks and clinical record staff) or designated clinical staff are responsible to ensure timely retrieval of adverse reaction documentation.
- All relevant clinical staff including prescribers, nurses, midwives and pharmacists are responsible to ensure identification and accurate documentation of:
 - Adverse reactions previously documented and/or reported by the patient.
 - Suspected adverse reactions associated with this hospital admission.

Associated documents

- Canterbury DHB Volume 2 - Legal and Quality
 - Incident Management Policy
- Canterbury DHB Volume 11 - Clinical
 - Clinical Record Requirements
- Canterbury DHB Volume 12 - Fluid and Medication Management
- Blood and Blood Products Policy - Acute Transfusion Reactions
- Drug Treatment Sheet (QMR0004)
- Adult National Medication Chart (NATAMC) or patient drug chart
- Preferred Medicines List (PML) (The Pink Book)
 - Assessing Adverse Reactions
- Adverse Drug Reaction (ADR) form (QMR0128)
- Adverse Reaction Sticker (QL00250)
- Incident Report Form (Ref. 1077)
- Management Guidelines for Common Medical Conditions (The Blue Book)
- Admission, Discharges, Transfers (ADT) IS Manual for Users of Homer, CareSys or Healthlink patient management systems
- MedicAlert Application for Membership

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Responsibilities on admission for capture and documentation

Admission Staff (Ward Clerks and/or Nursing Staff)

- Check the patient management system (Homer, CareSys or Healthlink) and Health Connect South (HCS) for previously documented adverse reactions - Print the page if any reactions are documented.
- Place the adverse reaction printouts in the front of the clinical notes (behind the green admission sheet) for clinical staff.
- Place a completed orange sticker on the front of the current clinical notes cover

Clinical Staff (Doctors, Pharmacists and/or Nursing Staff)

- Review electronic information from the patient management system, the clinical notes, referral letters and patient's (or whanau's) response regarding previous adverse reactions.
- Clinical staff must document (include date and sign) within the patient's current clinical notes whether the patient has
 - A previous reaction to a medicine, vaccine, therapeutic device, complementary therapy or food (food can potentially impact on medication prescribing). Include substance (preferably using generic name), reaction and date (where known).

OR

- No known previous reaction to any substance.

Clinical staff must document the substance and reaction on the orange adverse reaction sticker and place this on the patient's medication chart and/or fluid prescription chart OR

- Document the substance and reaction on the National Medication Chart

OR

- Tick the 'no' boxes on the patient medication chart or National Adult Medication Chart

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Clinical staff responsibilities prior to any drug/fluid

Administration

Clinical staff involved in the administration of any medicine, vaccine or therapeutic device will check with the patient (or whanau) that they have no known previous reactions to the medicine, vaccine or therapeutic device prior to each administration

Adverse reaction occurring while inpatients

Clinical staff reporting and documentation

If an adverse reaction occurs:

- Assess the clinical situation and act accordingly
- Medical staff are required to assess the patient as soon as possible post reaction
- A clinical staff member must update or add the Adverse Reaction Sticker (QL00250) on the patient's medication chart and front cover of current clinical notes(eg.QMR0004) or write on the appropriate boxes on the National Adult Medication Chart, date and sign
- Record adverse reaction details (substance and reaction) in the clinical record. Where possible use generic names.
- For reactions to foods or other substances refer to the [CDHB Food Allergy Management Policy Vol 11](#)
- For all severe reactions, inform a hospital pharmacist at first available opportunity.
- If appropriate, ensure an Incident Report Form is completed.

Particular medical staff responsibilities

- Assess the adverse reaction – refer to the PML for guidance.
- For serious reactions where the patient should avoid this product in the future, complete and sign an adverse reaction form (QMR0128) and leave the form in the front of the medical notes. Alternatively, complete the form on the Intranet (Clinical Info > Clinical Pharmacology > ADR reporting > complete form and print a copy to be filed in the patient's notes).

OR

- If your assessment determines that an adverse reaction is unlikely, cross out the adverse reaction information on the

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patient's medication chart – sign, write your name and date this clearly. Ensure this information is also documented in the clinical notes to avoid confusion.

- Discuss the benefits of Medic Alert with the patient if this is a serious reaction. Forms are available from the Pharmacy Department.

Referral requirements

- For adverse reactions involving anaesthetics, refer to the Department of Anaesthesia, Christchurch Hospital, for review.
- For severe reactions that are possibly anaphylactic or anaphylactoid, refer to the Department of Rheumatology/Immunology, Christchurch Hospital.

Particular pharmacist responsibilities

If the adverse reaction has been assessed by the medical staff to be serious and the patient should avoid this medicine in the future:

- Ensure an adverse reaction form (QMR0128) is completed and filed as follows:
 - Top copy – Centre for Adverse Reaction Monitoring (CARM) PO Box 913, Dunedin.
 - Second copy – patient clinical notes (in the front with other enduring information)
 - Third copy – the Pharmacy Department of a CDHB hospital.
- A designated adverse reaction pharmacist for all Canterbury DHB hospitals will:
 - Add serious/severe adverse reactions to the hospital's patient management system (e.g. Homer, CareSys or Healthlink).
 - Check the Clinical Pharmacology Home Site for electronically reported adverse reactions at least monthly and:
 - Send a copy to the appropriate hospital Pharmacy Department for filing.
 - Send a copy to the appropriate clinical record department for filing.
 - Send a copy to CARM.
- A designated pharmacist at each hospital will:
 - Maintain a file of adverse reaction reports for their hospital.
 - Add adverse reaction information, as received, to the ePharmacy dispensing system.

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- Advise the Canterbury DHB adverse reaction pharmacist of serious/severe adverse reactions to be added to the hospital's patient management system.

Responsibilities on Discharge

Medical Staff

- Must communicate suspected adverse reactions to the patient's General Practitioner and patient wishes regarding Medic Alert bracelet in the discharge summary.
- Must communicate suspected adverse reactions in transfer letters/ documentation to other hospitals and rest homes.

Pharmacist

If a yellow card (medicine list) is provided on discharge, ensure the patient's adverse reactions are documented on this card.

Clinical Record Department Staff

Ensure adverse reaction forms (QMR0128) and letters from CARM regarding specific patients, are filed at the front of the clinical record with other enduring documents.

References

- The HDC Code of Health and Disability Services Consumers' Rights Regulation 1996
- New Zealand Standard: Health Records (NZS 8153:2002)
 - Key Health Information Requirements

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